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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/998,042      | 11/30/2001  | Hermona Soreq        | 1567/66364/JPW/FHB  | 6063             |

7590 07/25/2003  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036

EXAMINER

CHISM, BILLY D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 07/25/2003

60

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/998,042

Applicant(s)

SOREQ ET AL.

Examiner

B. Dell Chism

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-17, drawn to a regulatory peptide having at least one of cell growth and cell differentiation activity, classified in class 514, subclass 2.
  - II. Claims 18-27 and 30, drawn to a method of using a regulatory peptide having at least one of cell growth and cell differentiation activity, classified in class 514, subclass 2.
  - III. Claim 28, drawn to a method of using a regulatory peptide having at least one of cell growth and cell differentiation activity to make a pharmaceutical composition, classified in class 514, subclass 2.
  - IV. Claim 29, drawn to method of using a regulatory peptide having at least one of cell growth and cell differentiation activity to induce synthesis of acetylcholinesterase mRNA, classified in class 514, subclass 2.
  - V. Claims 31-33, drawn to an antibody against a regulatory peptide having at least one of cell growth and cell differentiation activity, classified in class 530, subclass 387.1+.
  - VI. Claims 34-35, drawn to method of using an antibody to diagnose blood related disorders, classified in class 530, subclass 387.1+.
  - VII. Claims 36-37, drawn to method of using an antibody to diagnose male infertility, classified in class 530, subclass 387.1+.

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- VIII. Claims 38-46, 52, 54-57 and 63, drawn to an in vitro method for screening central nervous system affecting candidate drugs in a non-cell mixture, classified in class 530, subclass 350.
  - IX. Claims 38, 40, 47-51, 53, 54-57 and 63, drawn to an in vitro method for screening central nervous system affecting candidate drugs in a cell mixture, classified in class 530, subclass 350.
  - X. Claims 58-63, drawn to an in vivo method for screening central nervous system affecting candidate drugs, classified in class 514, subclass 2.
  - XI. Claims 64-65, drawn to a method of treating a stress-induced condition, classified in class 514, subclass 2.
2. The inventions are independent or distinct, each from the other because:

*Generic claims* 40 and 54-57 are drawn to subject matter of Group VIII and Group IX, thus, if Applicants elect either group VIII or IX then the generic claims will only be searched in-so-far as they pertain to the elected subject matter.

*Generic claim* 63 is drawn to subject matter of Groups VIII-X, thus, if Applicants elect any one of Groups VIII-X then the generic claims will only be searched in-so-far as they pertain to the elected subject matter.

Inventions Group I and Groups II-IV and VIII-XI distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of invention

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proteins of Group I can be used as biological markers, in immunoassays, binding assays or as a class of control.

The proteins of Group I are related to the antibodies of Group V by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarities of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The proteins of Group I are independent inventions from the methods of Groups VI-VII wherein the proteins of Group I are neither required in the method steps of Groups VI-VII nor made by the method steps of Groups VI-VII.

The methods of Groups II-IV, VI-VII and VIII-XI are independent one from the other because no Group requires the same components or steps as the other Groups.

Inventions of Group V and Groups VI-VII are distinct inventions as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group V can be used for protein detection or purification, in Western Blot, and in ELISA.

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The antibodies of Group V is independent from the methods of Groups II-IV and VIII-XI wherein the antibodies are not required or made in/by the method steps of Groups II-IV and VIII-XI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

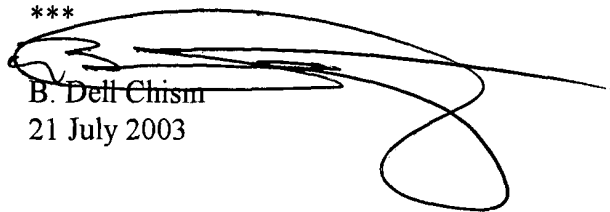
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

\*\*\*

B. Dell Chism

21 July 2003

A handwritten signature in black ink, appearing to read 'B. Dell Chism', with a long, sweeping horizontal stroke extending to the right and a large loop at the end.

  
BRENDA BRUMBACK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600